



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

March 4, 2013

MEMORANDUM

Subject: Efficacy Review for CDC Anti-Clog #1 Units, EPA Reg. No. 33427-4; DB
Barcode: D407343.

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Applicant: CDC Products, Corp.
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Port Washington, NY 11050-4661

Formulation from the Label:

<u>Active Ingredient</u>	<u>% by wt.</u>
Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride.....	20 %
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride.....	20 %
<u>Other Ingredients:</u>	60 %
<u>Total</u>	100 %

I. BACKGROUND

The product, CDC Anti-Clog #1 Units (EPA Reg. No. 33427-4), is a registered microbiocide for preventative maintenance for air conditioner condensate systems for industrial use only. The applicant requested an amendment to the registration of this product to add disinfectant claims for effectiveness against *Legionella pneumophila* under laboratory conditions. Registrant has been allowed to use a "Time Kill Assay for Antimicrobial Agents" protocol to conduct the study (see DP Barcode: 392277). The Agency requested the performance standard in the protocol be 99.9% reduction in 30 minutes. Study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package identified as D407343 contained a letter from the applicant's to EPA (dated November 5, 2012), EPA Form 8570-35 (Data Matrix), two studies (MRID 489900-01 and MRID 490681-01), and the proposed label (dated 11/05/2012).

II. USE DIRECTIONS

The product is for preventative maintenance for air conditioner condensate systems. Directions on the proposed label provided the following instructions for the preparation and use of the product:

1. Do not use in: Humidifiers, humidifier, sections of air conditioning systems or evaporative coolers.
2. Clean condensate pan and drain before installing unit.
3. Place unit in pan, pad side down.
4. In pans with drain connections, place unit under the cooling coil in the middle of pan length.
5. Unit must be in contact with condensate.
6. This unit is designed and approved only use in drain pans of Air Conditioning Systems and Refrigeration Systems.
7. For the control of growth of, or inactivate, legionnaire's Disease Bacteria replace unit every 2 months.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Products for Treating Industrial Water Systems to Control Legionnaire's Disease Bacteria

General: Direct or implied claims that a product will prevent growth or dissemination of Legionnaire's Disease Bacteria (LDB) in industrial water systems are not appropriate on the product label. Collateral literature may provide information concerning current knowledge and recommendations of the Public Health Service on this problem and/or laboratory test data showing presumptive effectiveness of the product against pure cultures of LDB, as follows:

- (1) Recommendations that cooling water systems should be regularly treated with antimicrobial pesticides effective in controlling slime and bacterial growth.
- (2) Laboratory test data showing ability of antimicrobial chemicals in the product to inactivate pure cultures of LDB in controlled experimental studies.

(3) Either of the above kinds of information should be qualified by statements that such recommendations or findings are presumptive, and that there is no evidence that any type of chemical treatment will control growth of LDB under actual operating conditions, reduce transmission of LDB, or prevent Legionnaire's disease.

Sample Claim for Technical Information Bulletins: "There is not enough scientific evidence to demonstrate that controlling the growth of Legionnaire's Disease Bacteria (LDB) in cooling tower water is necessary and/or adequate step in preventing the spread of this disease bacterium, although this possible mode of transmission cannot be entirely disregarded. Even in the absence of complete knowledge about LDB disease transmission and causal relationships of environmental LDB levels and disease outbreak, it is prudent to minimize slime growth and excessive bacterial contamination in cooling towers. This precaution is supported since the limited ecological studies on LDB have shown that the presence of the organism was usually associated with heavy fouling of cooling systems. By reiterating these established recommendations, this does not imply that any type of chemical treatment of air conditioning components will control the growth of LDB, reduce transmission of LDB, or prevent Legionnaire's disease. Regular treatment with (Product Name), following label directions will control the growth of fouling organisms in cooling tower water. [Insert statement (1) or (2) below.]

(1) (Product Name) has not been tested for effectiveness against LDB.

(2) In preliminary laboratory tests, (Product Name) has been shown to inactivate pure cultures of LDB. However, the ability of this formulation to control the growth of, or inactivate, LDB in operating water cooling towers exposed to ultraviolet light, organic material, other microbial contamination, and aeration has not been documented. These preliminary findings also do not address the problem of long-term preventive maintenance of water cooling tower.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 489900-01: "Time Kill Assay for Antimicrobial Agents, Test Organisms: *Legionella pneumophila* (ATCC 33153)", by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – October 15, 2012; amended November 19, 2012. Project Number A13890.

This study was conducted against *Legionella pneumophila* (ATCC 33153). One lot (Lot # 2570) of the product, Anti-Clog Units # 1, was tested using ATS Labs protocol # ACE01032612.TK (copy provided). A 72 hours culture of the test organism was adjusted to approximately 1×10^8 CFU/ml. One unit of the product was dissolved in 1000 ml of sterile deionized water, titrated for total quat content (498 ppm), then diluted to 20, 15, 10, and 5 ppm. Prepared test substance was used within three hours of preparation. A 9.5 ml aliquot of each test substance was transferred to a sterile tube for testing procedures. A 0.5 ml aliquot of the standardized inoculum was added to the test substance representing the start of the test exposure. The inoculated test substance was immediately mixed thoroughly using a vortex mixer. Each inoculated and mixed test substance was exposed for the exposure times of 5 minutes, 10 minutes, 20 minutes, and 30 minutes at ambient temperature (20°C). At each specified exposure time, the sample was mixed and a 0.1 ml aliquot of the inoculated test substance was transferred to 9.9 ml of neutralizer broth (10^0 dilution). Additional ten-fold dilutions were prepared in Butterfield's buffer. Using a standard microbiological spread plate count procedure, 1.0 ml aliquots of the 10^0 dilution and 0.1 ml of the 10^0 - 10^3 dilutions were

plated in duplicate on appropriate recovery medium. All subcultures were incubated at 35-37°C in 6.0% CO₂ for 3 days. Following incubation, the subcultures were visually examined for the presence or absence of visible growth and enumerated. Log₁₀ and percent reduction were determined for each exposure time. Controls included those for purity, sterility, viability, neutralization confirmation, and test population.

2. MRID 490681-01: "Evaluation of Solid Quaternary Ammonium Longevity in Simulated HVAC Drip Pan", by Joshua Luedtke. Non GLP study conducted at ATS Labs.

A test system was configured to expose the test substance to a consistent water flow. This system was comprised of a tap water supply (Eagan municipal tap water), a variable speed peristaltic pump, and a simulated HVAC drip pan containing the test substance. The influent water ran over the test substance contained in the drip pan to simulate the flow from an HVAC condenser coil. The effluent from the drip pan overflowed to a drain. The flow rate was set at 15 gallons per day \pm 30% (52.6 \pm 15.8 g of water/min, respectively). Water flow into the pan was continuous for 18 hours of each day during the test period, followed by 6 hours of no water flow. Twice per week, minimally, duplicate 60 second samples from the inflow tube were collected and weighed to verify the flow rate is within the specified range. Water samples were collected from the drip pan that overflows to drain immediately after flow into the drip pan begins at one hour and 24 hours after beginning flow into the drip pan and twice per week (at 2:30 pm), minimally, thereafter (for 90 days). Duplicate effluent samples were analyzed for Quaternary Ammonium Compound (QAC) concentrations per sampling time point.

V. RESULTS

MRID 489900-01

Test Organism	Concentration	Exposure Time	CFU/ml of Survivors	Log ₁₀ Survivors	Percent Reduction	Log ₁₀ Reduction
<i>Legionella pneumophila</i> (ATCC 33153) Population Control 6.5 x 10 ⁶ CFU/ml (6.81 Log ₁₀)	5 ppm	5 minutes	5.7 x 10 ⁵	5.76	91.2%	1.05
		10 minutes	4.4 x 10 ⁵	5.64	93.2%	1.17
		20 minutes	9.9 x 10 ⁴	4.99	98.5%	1.82
		30 minutes	3.2 x 10 ⁴	4.51	99.5%	2.30
	10 ppm	5 minutes	8.5 x 10 ⁴	4.93	98.7%	1.88
		10 minutes	9 x 10 ²	2.95	>99.9%	3.86
		20 minutes	<5	<0.70	>99.9999%	>6.11
		30 minutes	<5	<0.70	>99.9999%	>6.11
	15 ppm	5 minutes	6.2 x 10 ⁴	4.79	99.0%	2.02
		10 minutes	2.6 x 10 ³	3.41	>99.9%	3.40
		20 minutes	<5	<0.70	>99.9999%	>6.11
		30 minutes	<5	<0.70	>99.9999%	>6.11
	20 ppm	5 minutes	1.91 x 10 ⁴	4.28	99.7%	2.53
		10 minutes	5 x 10 ²	2.70	99.99%	4.11
		20 minutes	<5	<0.70	>99.9999%	>6.11
		30 minutes	<5	<0.70	>99.9999%	>6.11

MRID 490681-01: Titration Results for Evaluation of Solid Quaternary Ammonium Longevity in 90 days Simulated HVAC Drip Pan.

Date Performed	Time Under Test	QAC analysis (ppm)	Average ppm
3/7/12	Time 0	150,150	150
	1 hour	40,40	40
3/8/12	24 hours	320,310	315
3/13/12	Day 6	80,80	80
3/15/12	Day 8	4,4	4
3/20/12	Day 13	2,2	2
3/22/12	Day 15	25,25	25
3/27/12	Day 20	40,40	40
3/29/12	Day 22	40,20	30
4/3/12	Day 27	2,2	2
4/5/12	Day 29	12,12	12
4/10/12	Day 34	6,4	5
4/12/12	Day 36	28,30	29
4/17/12	Day 41	26,24	25
4/18/12	Day 42	28,28	28
4/24/12	Day 48	22,22	22
4/26/12	Day 50	10,10	10
5/1/12	Day 55	2,2	2
5/3/12	Day 57	10,8	9
5/9/12	Day 63	2,2	2
5/11/12	Day 65	16,16	16
5/15/12	Day 69	12,10	11
5/17/12	Day 71	4,4	4
5/22/12	Day 76	8,6	7
5/25/12	Day 79	<1,<1	<1
5/29/12	Day 83	4,2	3
5/31/12	Day 85	2,2	2
6/4/12	Day 89	2,2	2
6/5/12	Day 90	4,4	4

VI. CONCLUSION

1. The submitted efficacy data (MRID 489900-01) **support** the use of the product, Anti-Clog Units # 1, as a bactericide against *Legionella pneumophila* (ATCC 33153) on hard, nonporous surfaces, when production a 10 ppm total quat concentration in **10 minutes contact time**.
2. The submitted data (MRID 490681-01) **support** the use of the product, Anti-Clog Units # 1, when put in HVAC drip pan, as capable of delivering a minimum of 10 ppm total quat concentration when 15 gallons per day flow over the product, for 60 days (2 months).

VI. LABEL

1. The proposed label claims are **acceptable** regarding the use of the product, Anti-Clog Units # 1, as an effective bactericide against *Legionella pneumophila* (ATCC 33153) when at least **10 ppm** is maintained in water drip for **10 minutes**; also that, a **10 ppm minimum** concentration of

total quat concentration **is maintained for 2 months** (60 days) when approximately **15 gallons of drip water flow over Anti-Clog Units # 1 per day**. These claims are supported by the applicant's data.

2. The following revisions must be made to the proposed label:

- On page one of the proposed label, under the title, add "**in preliminary laboratory tests**" to "Control of legionnaire's disease bacteria" to read: "**Control of Legionnaire's Disease Bacteria in preliminary laboratory tests**".
- On page one of the proposed label, under Directions For Use, replace the verbiage under 7 with: "**7. Has been proven to control the growth of, or inactivate, Legionnaire's Disease Bacteria in experimental laboratory conditions for two months when approximately 15 gallons of water flow over Anti-Clog Units # 1 per day. We recommend replacing Anti-Clog Units # 1, every 2 months, if that is the intent.**"